K102050

Section III. 510(K) Summary

JUL 29 2010

Q-Switched Nd:YAG Laser System
Advanced Technology Laser Co., Ltd

(As required by 21 CFR 807.92)

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1. **Date Prepared:** March 22, 2010

2. **Sponsor Information:**

Advanced Technology Laser Co., Ltd
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Shanghai, 200240, China

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3. **Submission Correspondent**

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4. **Proposed Device Information**

Device Common or Usual Name: Q-Switched Nd:YAG
Device Trade or Proprietary Name: Q-Switched Nd:YAG Laser System
Model: GlobalCure-SC6
Classification Name: Laser Instrument, Surgical, Powered;
Regulation Number: 21 CFR 878.4810;
Product Code: GEX
Panel: 878 General and Plastic Surgery

5. Predicate Device

Spectra VRMII (Q-Switched Nd:YAG) (K073436)

6. Device Description

The Q-Switched Nd:YAG Laser System is a new device for 510(k) submission and shares the same indications for use and safety compliance, similar design features and functional features with the predicate device.

The Q-Switched Nd:YAG Laser System (GlobalCure-SC6) delivers laser at two wavelengths of 1064nm and 532nm. The double wavelengths cause maximum energy absorption by targeting the treatment area and minimum absorption by surrounding skin. In addition, the laser pulse duration is controlled to be equal to or shorter than the thermal relaxation time of the target, to minimize heat transfer to surrounding tissues.

The Q-Switched Nd:YAG Laser System covers control system, user interface, power supply, laser emission and delivery system, cooling system and safety features.

7. Indications for use

The Q-Switched Nd:YAG Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

532nm Wavelength: Removal of light ink (Red, Tan, Purple, and Orange) Tattoos
Removal of Epidermal Pigmented Lesions
Removal of Minor Vascular Lesions

Treatment of Lentigines
Treatment of Caf6-Au-Lait
Treatment of Seborrheic Keratoses
Treatment of Post Inflammatory Hyper-Pigmentation
Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength: Removal of dark ink (Black, Blue and Brown) Tattoos
Removal of Nevus of Ota
Removal of lightening of unwanted hair with or without adjuvant preparation
Treatment of Common Nevi
Skin resurfacing procedures for the treatment of acne scars and wrinkles

8. Substantial Equivalence

The Q-Switched Nd:YAG Laser System shares the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate device, Spectra VRMII (Q-Switched Nd:YAG) (K073436). In addition, a review of the predicate device demonstrates that the Q-Switched Laser System is safe and effective as the predicate device as they share equivalent wavelengths, and are used to perform the same indicated surgical procedures. Therefore the proposed device is substantially equivalent (SE) to the predicate device.

9. Testing

The Q-Switched Nd:YAG Laser System (GlobalCure-SC6) is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification, requirements and user's guide.
- IEC 60601-2-22:1995, Medical Electrical Equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment – Part 1: General requirements for safety.

- IEC60601-1-2:2001+A1:2004, Medical Electrical Equipment – Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.

The devices also comply with European Medical Directive 93/42/EEC and the US Federal Performance Standards 21 CFR 1002.10 Requirements (21CFR 1040.10 and 21CFR 1040.11 for Class IV Laser Products), Part 820 – Quality System Regulation, and have passed ISO9001 and ISO13485 System Certification.

Non-Clinical Conclusion:

Laboratory testing was conducted to validate and verity that the proposed device Q-Switched Nd:YAG Laser System (GlobalCure-SC6) met all design specifications and was substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Technology Laser Co., Ltd.
% Underwriters Laboratories, Inc.
Mr. Casey Conry
1285 Walt Whitman Road
Melville, New York 11747

OCT 25 2010

Re: K102050
Trade/Device Name: Q-Switched Nd:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 9, 2010
Received: July 21, 2010

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go tc http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102050

Section II. Indications for Use Statement

JUL 2 9 2010

510(k) Number: _____

Device Name: Q-Switched Nd:YAG Laser System

Indications for Use:

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Removal of Nevus of Ota

Removal of lightening of unwanted hair with or without adjuvant preparation

Treatment of Common Nevi

Skin resurfacing procedures for the treatment of acne scars and wrinkles

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use**_____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102050